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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

KIMBERLY GREMO
Plaintiff,
v.

BAYER CORPORATION, ET. AL.,
Defendants.

NO. 1:19-CV-13432-NLH-AMD

MOTION RETURN DATE:
October 21, 2019

DEFENDANTS GUERBET LLC AND LIEBEL-FLARSHEIM COMPANY, LLC'S BRIEF IN SUPPORT OF MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

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Counsel for defendants Guerbet LLC ("Guerbet") and Liebel-Flarsheim Company, LLC ("L-F") (collectively, the "Guerbet Defendants") submit this Memorandum in support of the Guerbet Defendants' motion to dismiss the First Amended Complaint (the "FAC") filed by Plaintiff Kimberly Gremo ("Plaintiff"), pursuant to Federal Rule of Civil Procedure 12(b)(6).

I. INTRODUCTION

Plaintiff's FAC fails to state facts upon which any claim for relief can be granted and should be dismissed.

As to all claims, Plaintiff fails to allege sufficient facts that would establish any plausible claim for relief against the Guerbet Defendants, as required by Federal Rule of Civil Procedure 8 and the Supreme Court's holdings in *Twombly* and *Iqbal*. Plaintiff indiscriminately asserts generalized allegations against the manufacturers and distributors of three chemically-distinct gadolinium-based contrast agents ("GBCAs") named as "Defendants," and fails to allege facts that would prove when or how the administration of any one of those products caused injury to her.

Plaintiff's New Jersey Products Liability Act ("NJPLA") claims – Counts I ("Failure to Warn") and II ("Design Defect") – are insufficient. Plaintiff's allegations, if accepted as true, do not establish that the Guerbet Defendants' GBCA product is the proximate cause of her purported injuries, or that she suffered physical harm from them. The failure to warn claim fails to allege a duty to warn of the risks complained of, or how or why the Guerbet Defendants could have altered the FDA-approved labeling of Optimark based on what was known and what was feasible at the time. Further, the allegations do not surpass New Jersey's "super presumption"

of adequacy of FDA-approved warnings. Finally, Plaintiff's Design Defect claim is preempted by federal law.

Count III ("Breach of Express Warranty") fails because it does not describe any express statement made to Plaintiff by the Guerbet Defendants.

Plaintiff's demand for punitive damages should be dismissed because punitive damages are unavailable as a matter of law in a product liability claim arising from use of an FDA-approved product.

II. FACTUAL BACKGROUND

Plaintiff's complaint was removed to this court on June 5, 2019. Dkt. 1. The Guerbet Defendants filed a motion to dismiss that complaint in its entirety on August 2, 2019. Dkt. 53. Before any ruling, Plaintiff filed an amended complaint on August 20, 2019. Dkt. 62. That same day, Plaintiff also filed an opposition to the Guerbet Defendants original motion to dismiss (Dkt. 65)[1] and to other defendants' pending motions to dismiss (Dkts. 63-64).

The Guerbet Defendants were, at certain times, involved in the commercialization of Optimark®, one of several GBCAs that have been administered in more than 450 million doses worldwide over several decades. GBCAs are FDA-approved prescription drug products used to enhance MRI images. *See* FAC. ¶¶1, 104. Plaintiff alleges that she received administrations of three

[1] By filing an amended complaint, Plaintiff mooted her original complaint and any pending motion related thereto. *See* § 1476 Effect of an Amended Pleading, 6 Fed. Prac. & Proc. Civ. § 1476 (3d ed.). The Guerbet Defendants hereby file a renewed motion to dismiss that responds to the allegations in the amended complaint. *See id.*; Fed. R. Civ. P. 15.

chemically-distinct GBCAs over a nine-year period (2007-2016). *Id.* ¶164. These products are allegedly manufactured by nine different defendants. *Id.* ¶¶4-61.

Plaintiff alleges that she suffers from a condition that she calls "Gadolinium Toxicity" or "Gadolinium Deposition Disease (GDD)." *Id.* ¶166. Plaintiff does not allege how this purported medical condition can be caused by GBCAs. She does not allege when or how any product caused physical injury, or what purported risks were known by the Guerbet Defendants at that time. The FAC refers collectively to "Defendants" without specifying which defendants' product or warnings contributed to her alleged injuries.

III. PLAINTIFF FAILS TO STATE ANY CLAIM UPON WHICH RELIEF CAN BE GRANTED UNDER FED. R. CIV. P. 12(B)(6)

A. LEGAL STANDARD

Dismissal is appropriate if a complaint fails to state a claim upon which relief can be granted. *See* Fed. R. Civ. P. 12(b)(6). A complaint must be dismissed under Rule 12(b)(6) if it does not "contain sufficient factual matter, accepted as true, 'to state a claim to relief that is plausible on its face.'" *Aschroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The federal rules of pleading demand "more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." *Twombly*, 550 U.S. at 555. A Plaintiff must allege facts that support the elements of a cause of action in order to "show that the claim is facially plausible." *Rodriguez v. Canada Dry Bottling Co., L.P.*, No. 14-6897, 2015 WL 5770502, at *2 (D. N.J. Sept. 30, 2015) (citations omitted). "[C]onclusory allegations or legal conclusions masquerading as factual

conclusions will not suffice to prevent a motion to dismiss." *Gen. Motors. Corp. v. New A.C. Chevrolet, Inc.*, 263 F.3d 296, 333 (3d Cir. 2001) (alteration in original; citation omitted). Moreover, sufficient facts must be pled as to each defendant. *See Burns v. City of Bayonne*, No. 12-6075, 2013 WL 3790305, at *7 (D. N.J. July 19, 2013) (finding dismissal warranted when complaint failed to specify which facts and which alleged actions by each defendant purportedly gave rise to each specific cause of action). The court, moreover, may not assume that the plaintiff can prove facts that she has not alleged. *See Associated Gen. Contractors v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983). Legal conclusions without adequate factual support are entitled to no assumption of truth. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1429-30 (3d Cir. 1997).

B. PLAINTIFF'S COMPLAINT FAILS TO ALLEGE SUFFICIENT FACTS TO SUPPORT A PLAUSIBLE CLAIM FOR RELIEF

1. The Complaint Uses Group Pleading and Fails the Notice Pleading Standard of Federal Rule 8

Federal Rule of Civil Procedure 8(a)(2) requires a "short and plain statement of the claim" to put defendants on sufficient notice of the allegations against them. When a complaint indiscriminately lumps the conduct of defendants together, it fails to comply with Rule 8. *See Galicki v. New Jersey*, No. 14-169, 2015 WL 3970297, at *2 (D. N.J. June 29, 2015). "Courts in this district generally agree that this type of "group pleading" does not satisfy Rule 8, because it does not place Defendants on notice of the claims against each of them." *Sheeran v. Blyth Shipholding S.A.*, No. CV 14-5482, 2015 WL 9048979, at *3 (D. N.J. Dec. 16, 2015)(citing cases). Vague "group pleading" fails to satisfy the plausibility requirements outlined by *Twombly*

and *Iqbal*. *See Ingris v. Borough of Caldwell*, No. CIV.A. 14-855 ES, 2015 WL 3613499, at *5-*6 (D. N.J. June 9, 2015).

Here, every substantive allegation is made collectively against all "Defendants" or all products. *See* FAC. ¶¶ 168-224. Plaintiff names eleven defendants in this action and alleges to have been administered three chemically-distinct GBCAs over a nine-year period, yet she casts all of her allegations broadly against all "Defendants" and products. Each allegation is directed at "relevant times" but fails to provide any insight as to when that might be. These vague allegations leave defendants to guess which allegations apply to each product and its respective manufacturers and distributors or to when the allegation pertains. Because the FAC fails to specify the conduct of any defendant, it does not comply with Rule 8(a)(2)'s notice requirement and should be dismissed.

2. The Complaint Fails to Allege Sufficient Facts to Establish a Plausible Claim for Relief as to the Guerbet Defendants

Even if the FAC met Rule 8's notice requirement – and it does not – it nonetheless fails to state facts sufficient to state a plausible claim. *Iqbal*, 556 U.S. at 662. The FAC is deficient because it fails to plead facts that would establish a plausible claim that any GBCA product has caused any cognizable injury to Plaintiff. Nowhere does the FAC describe when Plaintiff discovered her alleged injury; when she believes that injury occurred; when she was diagnosed with "gadolinium

toxicity, or Gadolinium Deposition Disease (GDD);" or which injection of which product caused her injury.[2]

The FAC also fails to allege facts that would establish that any GBCA, let alone Optimark specifically, is capable of causing physical injury to Plaintiff. The FAC provides a laundry list of symptoms that Plaintiff attributes to GDD. *See* FAC at ¶ 167. Yet, Plaintiff fails to allege how any of these injuries could be caused by the Guerbet Defendants' product.[3]

Plaintiff tries to obscure the missing link between the Guerbet Defendants' product and any specific injury by conflating "gadolinium toxicity or GDD" with Nephrogenic Systemic Fibrosis ("NSF") and "gadolinium retention." See id. ¶¶ 111-163. NSF and gadolinium retention have been studied and documented by medical researchers and physicians. These recognized medical phenomena are different from the purported disease "gadolinium toxicity or GDD" that the Plaintiff claims she suffers from. NSF has only been observed in a small percentage of patients with impaired renal function. See id. ¶ 111. Plaintiff concedes that she has normal kidney function, and therefore cannot develop NSF. See id. ¶165. As for gadolinium retention, the FDA has thoroughly studied the issue and specifically concluded that retention of gadolinium after clinical doses does not cause any known injuries. *See, e.g.*, FAC, ¶ 150 (quoting 2018 FDA approved labeling: "Consequences of

[2] The Guerbet Defendants do not concede that GDD or gadolinium toxicity are, in fact, recognized medical conditions. Nor do the Guerbet Defendants concede that GBCAs are capable of causing the types of injuries complained of by Plaintiff.

[3] For example, among the injuries Plaintiff attributes to GBCA's are: "teeth issues including darkened teeth and spots, cracking, and sensitivity" and "smell loss." Yet, the FAC never explains how either of these injuries could be caused by GBCAs.

gadolinium retention in the brain have not been established"); *see also,* Requests for Judicial Notice Dkt. 55, 56, Ex. B (December 2017 FDA statement: "Gadolinium retention has not been directly linked to adverse health effects in patients with normal kidney function").

Pages and pages of the FAC discuss research about NSF and gadolinium retention, along with purported scientific studies and regulatory actions that she asserts support her claims. *See* FAC ¶¶ 111-163. The FAC is rife with mischaracterizations of the medical sources it describes. For example, Plaintiff portrays actions of the U.S. FDA, European Medicines Agency ("EMA"), and other regulators as substantiating her claim that GBCAs can cause injury. *See, e.g.,* FAC ¶¶ 137, 146-150. Yet, after careful review, each of these agencies reached *an opposition* conclusion – that the existing medical and scientific evidence do *not* establish a causal link between GBCAs and *any* illness in renally-healthy patients. *See, e.g.*, FAC, ¶ 150 (2018-FDA approved label of each GBCA at §5.3: "Consequences of gadolinium retention in the brain have not been established" and "clinical consequences of gadolinium retention have not been established in patients with normal renal function"); 07/21/17 2017 EMA Final Opinion[4], cited by FAC at ¶¶110-11(concluding that "[t]here is currently no evidence that gadolinium deposition in the brain has caused any harm to patients").

[4] Available at https://www.ema.europa.eu/en/documents/press-release/emas-final-opinion-confirms-restrictions-use-linear-gadolinium-agents-body-scans_en.pdf (last visited August 9, 2019).

Additionally, Plaintiff frames discussion from the September 2017 FDA MIDAC as reflecting a "continuum" of gadolinium injuries, some of which can occur in people with normal renal function. *See id.* ¶¶147-48. The U.S. District Court for Arizona recently exposed this mischaracterization and chastised plaintiffs' experts for twisting those MIDAC statements.[5] *See Davis v. McKesson Corp., et al.*, No. CV-18-1157-PHX-DGC, 2019 WL 3532179, at *11-12 (D. Ariz. Aug. 2, 2019) (explaining why the MIDAC committee dialogue "does not endorse [the plaintiffs'] continuum conclusion"). The Arizona district court added that "mak[ing] such a strong but incorrect claim is concerning." *Id.*

The studies, individual case reports, and surveys cited throughout the FAC are also suspect and do not build any plausible causal link between gadolinium retention, on one hand, and the "gadolinium toxicity or GDD" injuries she complains of, on the other. *See, e.g.*, FAC ¶ 156 (referencing animal studies and anecdotal case reports from individuals without any explanation or commentary as to how these studies can be extrapolated to find *any* risk of *any* injury in humans with normal kidney function at clinical GBCA doses). Plaintiff's citations, at most, suggest that (a) gadolinium may be retained in the human body after receiving a GBCA, and (b) further research may be warranted. The scientific studies alleged do *not* state a plausible claim that gadolinium retention is or causes an injury. Indeed, when evaluating a similar complaint, the Eastern District of New York found dismissal appropriate because, "Plaintiff fails to plead a 'causal association' between any new information regarding gadolinium retention and an 'adverse effect', e.g., fibrosis." *McGrath v.*

[5] Notably, those GBCA plaintiffs share the same counsel as the Plaintiff here.

Bayer HealthCare Pharm. Inc., No. 18-CV-2134-RJD-VMS, 2019 WL 2582530, at *6 (E.D.N.Y. June 24, 2019).

Plaintiff fails to state any factual allegations that, if true, would establish that GBCAs cause the supposed medical condition "gadolinium toxicity" or *any* of the symptoms she allegedly suffers from. Plaintiff has pleaded quintessential "the defendant-unlawfully-harmed-me accusation[s]," which do not meet the federal pleading standards and therefore require dismissal. *Iqbal*, 556 U.S. at 678, 689.

C. COUNTS I (FAILURE TO WARN) AND II (DESIGN DEFECT) FAIL TO STATE A CLAIM UNDER THE NJPLA

Counts I and II fail as a matter of state law. In New Jersey, products liability claims are governed by the NJPLA, N.J.S.A. § 2A-58C, *et. seq*. A "product liability action" means "***any claim or action*** brought by a claimant for ***harm caused*** by a ***product***, ***irrespective of the theory underlying the claim***." N.J.S.A. § 2A:58C-1(b)(3) (emphasis added). The NJPLA defines "harm" as including: "(a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or other services or loss deriving from any type of harm described in subparagraphs (a) through (c) . . . " N.J.S.A. § 2A:58C-1(b)(2). Failure to warn and design defect claims arise exclusively under the NJPLA. N.J.S.A. § 2A:58C-2; *Nelson v. Biogen Idec Inc.*, No. 12-7317, 2013 WL 1700918, at *2 (D. N.J. Apr. 19, 2013).

1. Plaintiff Fails to Plead Any Cognizable Injury

Actual physical harm is required to bring an NJPLA claim. *Sinclair v. Merck*

& Co., 948 A.2d 587, 595 (2008). The mere potential of future harm is insufficient. *See id; Kury v. Abbott Labs., Inc.*, No. CIV.A. 11-803 FLW, 2012 WL 124026, at *6 (D. N.J. Jan. 17, 2012). Here, the retention of gadolinium in the body is not a physical injury. Nor does Plaintiff contend that it is. *See* FAC ¶149 (conceding that the U.S. FDA has not identified any injuries caused by gadolinium retention); *see also* Dkt. 55, 56, Ex. B 12/19/17 FDA Safety Announcement (concluding after review of medical literature that "[g]adolinium retention has not been directly linked to adverse health effects in patients with normal kidney function"). Plaintiff expressly concedes this point in her, now mooted, Opposition brief. *See* Dkt. 65 at n. 5 ("Plaintiff concedes that 'gadolinium retention alone'—that is, retention of gadolinium without claimed attendant symptoms or health effects—does not appear to constitute a compensable injury under the NLPLA …"). To the extent that FAC relies on gadolinium retention as a basis for recovery, it must be dismissed. *See, e.g., Sinclair*, 948 A.2d at 595 (2008) (dismissing NJPLA claims not based on physical injuries); *Kury*, 2012 WL 124026, at *6 (same); *Batchelor v. Procter & Gamble Co.*, No. CIV.A. 14-2424 JLL, 2014 WL 3749160, at *3 (D. N.J. July 30, 2014)(same).

2. Plaintiff Fails to Plead That Optimark Was The Proximate Cause of Any Injury

Under any NJPLA theory, plaintiff must show, at a minimum, amongst other things, that "the defect was the actual and proximate cause of the plaintiff's injury." *Worrell v. Elliott & Frantz*, 799 F. Supp. 2d 343, 350 (D. N.J. 2011) (citing cases)). As set forth above, Plaintiff has failed to allege facts which, if assumed true, plausibly establish that the Guerbet Defendants' GBCA proximately caused any

specific injury and her claims should be dismissed. *See McGrath*, 2019 WL 2582530 at *6.

3. Plaintiff Fails to Plead a Failure to Warn Claim Under the NJPLA

Under the NJPLA a "manufacturer may be liable for harm caused by a failure to warn if the product does not contain an adequate warning or instruction." *Sich*, 2017 WL 4407930, at *3. "[B]efore reaching the question of whether the product contained an adequate warning, plaintiff must first establish that there was a latent danger of which the manufacturer had a duty to warn." *Toms v. J.C. Penney Co.*, 304 F. App'x 121, 127 (3d Cir. 2008). A manufacturer must have "sufficient knowledge to trigger the duty to provide a warning of the harmful effects of its product." *Becker*, 2015 WL 268857, at *4. Where a complaint fails to set forth these basic factual elements it should be dismissed. *See id.* at *5.

The majority of the supposed warnings that Plaintiff alleges she should have received relate to either gadolinium retention[6] (not the injury plaintiff complains of and not a cognizable harm under the NJPLA)[7] or NSF (a condition in patients with impaired kidney function that Plaintiff admits she was adequately warned of). FAC at ¶174. With respect to injury, Plaintiff vaguely contends that the Guerbet

[6] FAC at ¶ 174 (a) – (e), (h) and (i).

[7] Plaintiff's failure to warn theory depends upon the distinction between gadolinium retention and injury. Plaintiff admits that she continued to use the Optimark product even ***after*** its label was updated to include a discussion of gadolinium retention. *See* FAC at ¶146 (alleging use of Optimark on December 22, 2016); and FAC at ¶¶ 152-53 (admitting that in August 2016 the Optimark label contained a discussion of gadolinium retention including the statement: "gadolinium deposits may be present for months or years in bone, liver, skin, brain, and other organs.").

Defendants had a duty to warn regarding: "GDD," or more generically, any "adverse effect." *See* FAC at ¶174(a) & (g). Yet, despite claiming six exposures to Optimark over a nine-year period (2007-2016), she fails to allege when that duty to warn arose. *Id.* (alleging only "at times relevant"). She does not link the duty to any defendant's awareness at any specific time of any plausible risk.

Even today, there are no known injuries associated with the use of GBCAs in patients with normal renal function. *See supra* at Part III-B; *see also* Dkt. 55, 56, Ex. B (December 2017 FDA statement: "Gadolinium retention has not been directly linked to adverse health effects in patients with normal kidney function"). Accordingly, Plaintiff fails to allege that the Guerbet Defendant had at any time (let alone from 2009-2016) a duty to provide the warning(s) she asserts should have been provided regarding any injury.

Additionally, Plaintiff fails to allege that the Guerbet Defendants had any ability to modify the FDA-approved label with Plaintiff's desired warning. Where, "FDA would not have approved a change to the drug's label [this fact] pre-empts a claim, grounded in state law, that a drug manufacturer failed to warn consumers of the change-related risks associated with using the drug." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019).

Plaintiff suggests that in order to demonstrate impossibility preemption, the Guerbet Defendants must show that they requested Plaintiff's preferred warning and that the FDA rejected this request. FAC ¶ 162. But that is not the correct legal standard. "Clear evidence" that the FDA would not have approved such a warning is necessary. *Albrecht*, 139 S. Ct. at 1672. Clear evidence requires a showing that

the FDA was informed of the "justification for the warning required by state law" and the FDA would not allow such a warning. *Id.* Such clear evidence can take many forms. *See Cerveny v. Aventis, Inc.*, No. 17-4204, 2019 WL 3763441, at *3 (10th Cir. Aug. 9, 2019) (third-party citizen petition may constitute "clear evidence").[8]

Here, Plaintiff concedes that FDA was fully informed. *See* FAC at ¶ 146 ("FDA and the GBCA industry collaborated in an advisory committee meeting – the Medical Imaging Drugs Advisory Committee (MIDAC)"). "The focus of MIDAC's inquiry was the connection, if any, between the retention of GBCAs or gadolinium in the body and various symptoms reported in patients with healthy kidneys." *Davis v. McKesson Corp.*, No. CV-18-1157-PHX-DGC, 2019 WL 3532179, at *5 (D. Ariz. Aug. 2, 2019). "After considering all of the evidence and hearing presentations from scholars, experts, and patient advocacy groups, MIDAC unanimously concluded that the medical and scientific evidence does not establish that GBCAs cause GDD." *Id.* This conclusion – "clinical consequences of gadolinium retention have not been established in patients with normal renal function" – is embedded in the 2018 label change that Plaintiff points to as supporting her claim. FAC at ¶ 150. These

[8] The Tenth Circuit explained that to invoke impossibility preemption, a defendant need not show that the FDA expressly rejected defendant's request. "[Defendant] argues a different ground to show that the FDA would have rejected the [plaintiff's] proposed warning. Unlike *Wyeth*, [defendant] is not left to show clear evidence that the FDA would have rejected any unilateral label change under the CBE regulation, but [defendant] has a separate avenue—the FDA's unequivocally having rejected [a third-party] citizen petition advocating for the warning that [plaintiffs] now assert. We see nothing in *Wyeth* or *Albrecht* excluding [defendants] from justifying preemption on this basis."

undisputed facts constitute "clear evidence" that Plaintiff's suggested warnings related to injury would not have been approved by the FDA.

Further, under federal regulations, absent FDA approval, a manufacturer may alter product warnings only if "the change is designed to 'add or strengthen a ... warning' where there is 'newly acquired information' about the 'evidence of a causal association' between the drug and a risk of harm." *Albrecht*, 139 S. Ct. at 1673 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A)). Plaintiff cites studies that she labels as "newly acquired evidence," but none of these demonstrate that clinical doses of GBCAs cause any injury in patients with normal renal function. *See* FAC at ¶ 156.[9]

At most, Plaintiff's allegations would establish that trace amounts of gadolinium can be retained in patients with normal renal function. Plaintiff's allegations, however, would not establish any risks of injury associated with gadolinium retention. *See McGrath v. Bayer HealthCare Pharm. Inc.*, No. 18-2134, 2019 WL 2582530, at *4 (E.D.N.Y. June 24, 2019) ("Because Plaintiff's failure-to-warn claims depend upon [Defendants'] failure to warn of the risks of gadolinium retention, plausible allegations that relate only to the fact of gadolinium retention do not suffice" to plausibly allege the existence of newly acquired information that could have justified Defendants' revising the Product label to warn of any injury through the CBE regulation).

[9] Plaintiff again resorts to collapsing gadolinium retention with resultant injury. Of the twenty-nine subparts to paragraph 156, ten relate solely to gadolinium retention. While the others involve routes of administration (e.g. in-utero, intrathecal, epidural, etc.) or dosing regimens (e.g. multiple daily exposure) that are not at issue here. *See* also, *supra* at (B)(2) (explaining that Plaintiffs allegations do not state a plausible claim that gadolinium retention is or causes an injury).

Additionally, the NJPLA provides that FDA-approved warnings that accompany pharmaceutical products are presumed to be adequate as a matter of law. *See Nelson v. Biogen Idec, Inc.*, No. 127317, 2018 WL 1960441, at *10 (D. N.J. Apr. 26, 2018). "The [New Jersey] Supreme Court has further described [this] presumption as a 'super-presumption, that can be rebutted only in 'rare' cases.'" *Id.* at *10 (D. N.J. Apr. 26, 2018) (quoting *Kendall v. Hoffman–La Roche, Inc*., 209 NJ. 173, 197 (NJ 2012)). "[C]ompliance with FDA standards should be virtually dispositive" of failure to warn claims. *Perez v. Wyeth Labs. Inc*., 161 N.J. 1, 25, 734 A.2d 1245, 1259 (1999). Plaintiff does not allege that the Guerbet Defendants failed to provide the FDA-approved labeling; rather, she concedes the FDA-approved labeling does not include the warning she desires. *See* FAC ¶88. Plaintiff fails to allege facts that can overcome this "super-presumption" of adequate warning.

Next, New Jersey applies a learned intermediary standard. This means that a "drug or medical device manufacturer fulfills its duty to warn the ultimate user of its product when it provides a physician with an adequate warning about any dangerous propensities that product may have." *Seavey v. Globus Med., Inc*., No. 11-2240, 2014 WL 1876957, at *10 (D. N.J. Mar. 11, 2014). The duty to warn is owed to the prescribing physician rather than the patient. *See Nelson*, 2018 WL 1960441, at *9. Plaintiff's allegation that defendants failed to provide proper warnings to "users of linear GBCAs, including Plaintiff" fails as a matter of law. *See* FAC ¶173.

4. Plaintiff Fails To Plead A Design Defect Claim Under the NJPLA

"Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 477 (2013). Federal regulations prohibited the Guerbet Defendants from altering the formulation of their GBCAs. *See* 21 C.F.R. § 314.70(b)(2)(i). Accordingly, Plaintiff's design defect claim is preempted. *Yates v. Ortho-McNeil-Janssen Pharm., Inc*., 808 F.3d 281, 298 (6th Cir. 2015) (federal law prohibits defendants from altering their design once approved). Here, Plaintiff asserts that the product was defective at the time they left the control of Defendants (*i.e.*, after receiving FDA approval). FAC ¶186. The Guerbet Defendants were prohibited by federal regulation from altering the product design at this time.

Even if Plaintiff's design defect claim addressed pre-approval sales of a GBCA (it does not) the claim still fails for two reasons. First, a claim of pre-approval design defect is a claim that the manufacturer never should have sold the product at all. The U.S. Supreme Court explained that such a "stop-selling rationale" cannot overcome preemption. *Bartlett*, 570 U.S. at 489. Claims that a particular drug-product should have never been developed or sold in the first-place fall within this ambit and should be dismissed. *See also Yates*, 808 F.3d at 300 ("In contending that defendants' pre-approval duty would have resulted in a [product] with a different formulation, [Plaintiff] essentially argues that defendants should never have sold the

FDA-approved formulation of [the product] in the first place. We reject this never-start selling rationale for the same reasons the Supreme Court in *Bartlett* rejected the stop-selling rationale").

Second, irrespective of preemption, Plaintiff fails to adequately plead a design defect claim under the NJPLA. In order to make out a design defect claim, Plaintiff must state facts that would establish the product was "designed in a defective manner." N.J.S.A. § 2A:58C-2. To do so, a "plaintiff must prove either that the product's risks outweighed its utility or that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm." *Lewis v. Am. Cyanamid Co.*, 155 N.J. 544, 570 (1998). Importantly, under the NJPLA, a manufacturer is not liable for a design defect, if "[a]t the time the product left the control of the manufacturer, there was not a practical and technically feasible alternative design…" N.J.S.A. § 2A:58C-3. Accordingly, "[i]n order to succeed on a design defect claim, a plaintiff is required to prove that a practical and feasible alternative design existed that would have reduced or prevented [her] harm." *Mays v. Gen. Binding Corp*., No. 11-5836, 2013 WL 1986393, at *6 (D. N.J. May 10, 2013). Plaintiff alleges that Optimark should have been designed as a macrocyclic as opposed to linear GBCA. FAC ¶191. But Plaintiff does not explain how a macrocyclic design would have prevented *her* purported injuries. At most, the allegations in the FAC assert that a macrocyclic design could have resulted in less gadolinium retention—but gadolinium retention is not an injury. *See supra.*

D. COUNT III (BREACH OF EXPRESS WARRANTY) FAILS AS A MATTER OF LAW

Count III (Breach of Express Warranty) fails because it does not allege any express statement made by the Guerbet Defendants to Plaintiff—let alone any statement of any warranty. To prevail on her breach of express warranty claim under New Jersey law, Plaintiff must show: "(1) that [the] [d]efendant made an affirmation, promise, or description about the product; (2) that this affirmation, promise or description became part of the *basis of the bargain* for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." *Arlandson*, 792 F. Supp. 2d 691 at 706; *see* N.J.S.A. § 12A:2—313. A plaintiff cannot simply recite the elements of the claim. *Simmons v. Stryker Corp.*, No. 08-3451, 2008 WL 4936982, at * 2 (D. N.J. Nov. 17, 2008) (emphasis added). Rather, a plaintiff must allege facts to suggest that a warranty existed. *See id.* (citing *Heisner ex rel. Heisner v. Genzyme Corp.*, 2008 WL 2940811, at *8-9 (N.D. Ill., July 25, 2008) (dismissing plaintiff's express warranty claims for failure to specify any specific statement that formed any warranty).

Plaintiff must "identify the actual ***language*** or source of th[e] warranty, or specify when the warranty was in effect" and must further "provide the ***language*** of any advertisements, promotional or marketing materials, point[-]of-sale displays, or product specifications" that contained the alleged warranty. *Fishman v. Gen. Elec. Co.*, Civ. No. 2:12-00585, 2013 WL 1845615 at *5 (D. N.J. Apr. 30, 2013) (citing *Arlandson*, 792 F. Supp. 2d 691 at 707) (emphasis added); *see also Simmons*, 2008 WL 4936982, at * 2 (dismissing express warranty claim that was "devoid of any

'factual matter' to support the existence of an express warranty"); *Parker v. Howmedica Osteonics Corp.*, Civ. No. 07-2400, 2008 WL 141628, at *6 (D. N.J. Jan. 14, 2008) (dismissing express warranty claim against medical device manufacturer based on alleged "press releases" and "assurances of safety").

Plaintiff fails to allege any express warranty. She asserts vaguely that "product labeling, marketing, advertising, promotion, and educational efforts" by all Defendants, somehow constitute an express warranty. She hasn't identified a specific statement that formed any bargain. *See* FAC ¶209 (containing only vague descriptions of the purported warranty, such as "[defendants warranted that] Linear GBCAs are generally safe for use"). As the court in *Parker* explained, "[t]hese statements are exactly the type of bald assertions that fail to give [defendants] fair notice of what the claim is and the grounds upon which it rests." 2008 WL 141628, at *6 (quoting *Twombly*, 127 S. Ct. at 1959). Accordingly, her breach of express warranty claim fails and should be dismissed. *Parker*, 2008 WL 141628, at 6.

E. PLAINTIFF CANNOT SEEK PUNITIVE DAMAGES UNDER NEW JERSEY LAW

Punitive damages are not an independent cause of action. Punitive damages are an additional remedy available under an existing cause of action. *See* New Jersey Punitive Damages Act, N.J.S.A. § 2A:15-5.15 ("Nothing contained in this act is to be construed as creating any claim for punitive damages which is not now available under the law of this State."). Accordingly, punitive damages are available only if they authorized under Plaintiff's operative legal theory.

Punitive damages are expressly barred by the NJPLA, and the Court should dismiss Plaintiff's request seeking them. *See* N.J.S.A. § 2A:58C–5c. The NJPLA provides that "[p]unitive damages shall not be awarded if a drug or device which caused the claimant's harm was subject to premarket approval . . . by the federal Food and Drug Administration . . . and was approved." *Id.* The plain language of the NJPLA provides "in no uncertain terms—that punitive damages '**shall not be awarded**' in a products liability case based on an FDA-approved drug." *Nelson*, 2013 WL 1700918 at *2 (emphasis in original). The NJPLA reflects the Legislature's clear intent "that FDA approval of prescription drugs conclusively prohibits an award of punitive damages in products liability actions." *Rowe v. Hoffman-La Roche, Inc.*, 917 A.2d 767, 774 (N.J. 2007). [10]

Plaintiff concedes that OptiMARK® is an FDA-approved prescription drug. *See* FAC ¶54. Plaintiff's claims originate under or are subsumed by the NJPLA. *See*

[10] The statute does establish one exception –not alleged by Plaintiff– where the "product manufacturer knowingly withheld or misrepresented information required to be submitted under [FDA] regulations, which information was material and relevant to the harm in question." N.J.S.A. § 2A:58C–5c; *Cornett v. Johnson & Johnson*, 998 A.2d 543, 567 (App. Div. 2010), (internal quotations and citations omitted) ("Instead of making punitive damages an aspect of a common-law claim for compensatory damages … the Legislature enacted a separate statute that was 'narrowly drawn' with 'the single focus upon fraud on the FDA' as unlawful conduct that the State had an interest in punishing"). But Plaintiff cannot invoke this exception because claims of fraud on the FDA are preempted by federal law. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Both New Jersey courts and courts in this District have consistently held that this exception to the prohibition of punitive damages under the NJPLA is preempted by federal law. *See Cornett*, 998 A.2d at 567; *Nelson*, 2013 WL 1700918 at *3; *Mendez v. Shah*, 28 F. Supp. 3d 282, 305 (D. N.J. 2014).

supra. Accordingly, Plaintiff's request falls squarely within this exclusion on punitive damages, and the Guerbet Defendants are not subject to them. *See*, *e.g.*, *Nelson*, 2013 WL 1700918 at *2 (dismissing punitive damages claims against FDA-approved drug product via 12(b)(6) motion). Accordingly, Plaintiff's request for punitive damages should be dismissed.

IV. CONCLUSION

For the aforementioned reasons, Defendants Guerbet LLC and Liebel-Flarsheim Company, LLC respectfully request that this Court dismiss Plaintiff's First Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(6).

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Respectfully submitted,

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